

04P-0266_emc-000001

Make Healthy Choices: Avoid using petrochemical-derived
[wilworks@lmi.net]
Sent: Monday, June 28, 2004 3:12 PM
To: FDA; NIOSH; NET
Subject: Make Healthy Choices: Avoid using petrochemical-derived fragrance products;
99P-1340; 2004P-0266

To FDA Dockets --

I am copying you with a message I had sent to: National Women's Health Information Center.

FDA -- Please register in support of:
Citizens' Petition Docket Number 99P-1340
and
Citizens' Petition Docket Number 2004P-0266

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Dear Folks with National Women's Health Information Center --

I came into your site, via NIOSH's "Steps to a Healthier U.S. Workforce", Related Links

I found your Steps to Healthier Women -- <http://www.4woman.gov/pub/steps/> -- and that page triggered the following thoughts.

To the table on ways to improve health, I suggest you add, fragrance products, in the category: "Make Healthy Choices." Right now that reads: "Avoid tobacco and drugs as well as the abuse and underage use of alcohol and make smart and safe choices in your everyday life." That line "make smart and safe choices in your everyday life" is good, but much too vague if you are hoping to alert people to choose products without chemicals that are known carcinogens, hormone disrupters, irritants, neurotoxins, sensitizers and teratogens.

I write to suggest that "Make Healthy Choices" be edited to read:

"Avoid tobacco, drugs and petrochemical-derived fragrance products, as well as the abuse and underage use of alcohol and make smart and safe choices in your everyday life."

To use the term "petrochemical-derived fragrance" means you will be borrowing from the line used by the Dept. of the Interior, in which it states that a "green" product "Must not contain petrochemical-derived fragrance." (See "Guidance and Training on Greening Your Janitorial Business"; Chpt. 2: "Traditional Versus 'Green' Cleaning Products" at <http://www.doi.gov/greening/sustain/trad.html>)

By now, there is enough good information out, from reputable researchers and doctors, that warrants the alerting of women at the national level to the health harms associated with the myriad of scented products they use. Fragrance products they use on themselves, on their children, for their cleaning and maintenance chores, including laundry and dishes, and purchase for their family members to use as cosmetics and personal care products. Air indoors and out is polluted by perfumed

products. And soaring rates of various unexplained illnesses demand a look at the concoctions called "fragrance."

Back in May 1999, the Environmental Health Network -- <http://www.ehnca.org> -- petitioned the US Food and Drug Administration based upon analyses of perfumes which showed the toxins found. Couple the toxins with the fact that the labels of the popular perfumes did not contain the FDA's required alert: "WARNING: The safety of this product has not been determined," and the petition was born. (Source for warning: "FDA Authority Over Cosmetics" <http://vm.cfsan.fda.gov/~dms/cos-206.html>)

That petition -- Docket Number 99P-1340 -- still sits, but remains open and receiving comments from the public about the harmful effects of the perfumes. The adverse events suffered happen whether they are or have been used personally, or are the result of second- or third-hand reactions from scented products used by others.

The industry had not thoroughly tested the products, which are crafted to be inhaled (smelled), for effects upon inhalation. The industry's focus had been on the dermatological reaction of the primary user . . . not even giving a tinker's damn about folks who suffered dreadfully from airborne contact dermatitis. Of course, the FDA did nothing about testing because it could do nothing about testing . . . the FDA cannot even require pre-market testing.

The fragrance industry is protected in three ways, as I see it.

1) The fragrance industry is self-regulated -- that works for folks who believe the fox CAN guard the hen house -- and claims to "thoroughly" test. For the most part, that has meant for dermatological reactions of the primary user. It also has claimed that the small amount of a given chemical can cause no harm . . . while not looking at the combinations of chemicals, nor the fact that many such chemicals are inhaled and absorbed and bioaccumulate on a daily basis from many such products. Of course, one branch greets a visitor with the message that fragrances and their ingredients are safe and wholesome. Where is their proof? (Fragrance Materials Association at <http://fmafragrance.org>)

2) The fragrance industry is protected by trade secret laws, which only shield it from an informed consumership, not from "rip-off" scents. Obviously.

3) The fragrance industry is further protected by fragmentation of what little government authority exists. The FDA is over fragrances, but not really. The EPA is over air pollution indoors and out -- and water pollution -- but has been hesitant to get embroiled when it comes to scented products because they are in the FDA's bailiwick. And while the CPSC is over scented products like fabric softeners, it has remained aloof from the complaints it has received over the years . . . for don't you know that is in the EPA's sector because it manifests itself in air pollution both during use in the laundry facilities and when the clothing is worn, but ultimately it is a fragrance, so guess what, we're back to the FDA! In the meantime, the already fragrance-sensitized public is being taken for a ride . . . on a not-so-merry-go-round.

In the early 1990s, we learned from Lynn Lawson through her book, "Staying well in a Toxic World: Understanding Environmental Illness, Chemical Sensitivities, Chemical Injuries, and Sick Building Syndrome," and her quote of Ralph Nader in "Being

Beautiful" -- "Due to some adroit lobbying years ago by the cosmetic industry, the FDA has to beg for safety, rather than demand it." ("Being ..." by Center for the Study of Responsive Law, copyright 1986; "Staying..." copyright 1993; Noble Press; Page 287.)

Alas, the FDA doesn't even do that begging for safety!

The FDA cannot require pre-market testing and it does not test. Any word from industry to FDA about related injuries from fragrance/cosmetic products is strictly voluntarily released information. The industry voluntarily recalls harmful products . . . the FDA is forbidden to institute recalls, without first proving cause in a court of law. The FDA can do one thing toward informing the public, yet it does NOT do it. The FDA has a requirement for a warning message on labels of products released to market without substantiation of safety, but it does not enforce its own regulation.

Regarding the industry's claim of "thorough testing" . . . The industry announced in February 2002 that it had begun to test for effects upon inhalation and for systemic effects. That was a good three decades following the move from fragrances derived mainly from plant and animal essences to those crafted mainly from petrochemical derivatives. ("Scents and sensitivities ..." by Francesca Lyman; Feb. 6, 2002, MSNBC CONTRIBUTOR, <http://www.ehnca.org/FDApetition/flscents.htm>)

There had been no thought given -- at least not formally recognized -- to effects upon the respiratory system (manifesting as asthma, sinusitis, laryngitis, rhinitis, etc.) or upon the brain (fragrance products contain neurotoxins) or the heart and circulatory system (precipitously dropping blood pressure or the other extreme, high and spiking blood pressure with the resultant heart problems). These resultant diseases are common among the already fragrance sensitized. Nor was there thought given (translation: studies of or thorough testing for) systemic effects, yet some fragrance chemicals bioaccumulate and are known carcinogens. Musks for instance are found in breast tissue, downstream in mother's milk AND downstream from waste treatment facilities where they are affecting fish and wildlife . . . and other people, one may presume.

There was no thought given to adverse events suffered by those who do not choose to use perfumes and perfumed products. Despite the fact that that choice is made because their health will not tolerate such chemical assaults, and their astute doctors have recommended the impossible: AVOID FRAGRANCES.

Yet, by virtue of the fact that modern, petrochemical-derived fragrances are also concocted to waft further and last longer on the ambient air -- thank phthalates in part for that -- everyone becomes a user . . . from the embryonic and fetal stage, through all phases of development and into old age. Fragrances have become ubiquitous. Manufactured fragrances are not essential to life. On the other hand, they have proved to be harmful to millions of people. Yet they are marketed without government pre-testing and without any warning whatsoever. Maybe because there is no government warning, the US Department of Justice's John L. Wodatch (<http://www.usdoj.gov:80/crt/foia/tal605.txt>) has deemed perfumes a personal choice issue, so that even when the already chemically injured are seeking health care, one is subjected to the harmful volatilizing organic compounds from fragrances that are not necessary for job performance of doctors, nurses or administrative staff.

Thorough testing? Surely there was evidence of adverse events as evidenced by William Troy's 1977 Doctoral Dissertation "The comparative respiratory irritation
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potential of fourteen fragrance raw materials." Troy, who is gainfully employed by the fragrance industry, wrote: "It has been demonstrated that fragrance raw materials can be successfully evaluated for respiratory irritancy by use of the whole body plethysmographic technique." (Unpublished report to RIFM. 1977
References: Troy W.R.)

What about industry testing that indicated health problems for users AND nonusers? Did the industry find ill effects and then veer away from further study as it surely would put a crimp in their plans for a megabillion dollar industry if they found harmful effects? Where are the results of all tests? What does the industry truly define as "thorough" testing. (Interestingly, the pharmaceutical industry wouldn't be fairing so well either, had it not been for the FDA's relaxation of drug advertisements along with the increased sales of fragranced products that create so many of the health needs served by the drug industry.) To not look for adverse events for users and nonusers is not the same as there being no adverse events suffered by users and secondary users of fragrance products.

As it is, the public MUST take it on blind faith that the fragrance (and flavors) industry's products are safe to use as marketed. There is no proof from the industry, nor from our government agencies, that these products are safe to use. The inhalation, absorption and systemic effects of fragrance chemicals are totally uncontrolled. I believe that the required public's blind faith in the industry and its products, in the face of soaring rates of various "unexplained" diseases and premature deaths, is risky business.

I suggest that NWHIC take a look at petition 99P-1340 and some of the letters received by the FDA. Surely, there should be some interagency co-operation. The petition is home on two sites: EHN's at <http://www.ehnca.org/FDApetition/bkgrinfo.htm> and that of my friend and colleague, Betty Bridges, RN and her renowned Fragranced Products Information Network at <http://www.fpinva.org/petition99P1340.htm>

Then take a look at the demographics for "unexplained" soaring cases of asthma. Research the information available about the fragrance industry targeting those same groups of people . . . not statistics, PEOPLE! People among the populations of African-Americans and Hispanics and, all children -- pre-teen and teen is a huge market. Also, look at the stats about soaring rates of asthma among the elderly. I'll bet you'll find those elderly folks are subjected to scented cleaners, air "fresheners" (what a misnomer that is!!), pesticides, laundry products and scented personal care products and perfumes used by those who care for them, not to mention those who themselves still use perfumes because they think those products are proved safe for use before marketing.

We all have a public health issue on our hands.

Some of us who are the harbingers have been discriminated against in so many ways they can't be cataloged; there is no recompense. And worse, we cannot reclaim our health, just hope to live healthier in a lifestyle that has had to become a "new normal." Many of us have lost dear friends to chemical injury. Those still living and relatively healthy -- often because they are no longer working -- are the ones that have stepped up to serve the needs of growing numbers of people in this country and worldwide. We are the ones that have developed websites to share the information. And a couple of us are the ones who put our money into purchasing an analysis of a popular perfume. Something our government agencies charged with

protecting public health should have done a long time ago. Blind faith must go. Open the eyes and the minds. Or, at the very least, warn the public that the cosmetics and fragrances they choose to use have not been substantiated for safety.

None of this should be a surprise to anyone, following the 1978 -- we're creeping up on 30 years here, folks! -- General Accounting Office scathing report on the safety of cosmetics, the 1986 report, Being Beautiful, the 1986 report to Congress titled Neurotoxins: At Home and the Workplace (Report by the Committee on Science and Technology. U.S. House of Representatives, Sept. 16, 1986) [Report 99-827] (For a few excerpts, see: <http://users.lmi.net/wilworks/ehnlrx/n.htm#Neurotoxins>)

And now, as of June 14, 2004, we have the Environmental Working Group's petition of the FDA on the safety of cosmetics . . . available on their site called Skin Deep -- <http://www.ewg.org/reports/skindeep/> Furthermore, GreenPeace UK is analyzing fragrances. See Eternity, among several, at <http://www.greenpeace.org.uk/Products/Toxics/chemicalhouse.cfm?producttypeid=5&productid=139>

Instead of castigating those who showed early signs of chemical poisoning by commonly used consumer products, we should have been viewed as Human Observational Studies -- for after all we have served as the unwarned, unpaid, unrecognized industry and government guinea pigs. From this point forward, to not clearly inform women -- and men -- of the dangers associated with breathing the air polluted by perfumes and perfumed products, as we are warned about other chemicals, seems to me to be a matter of dereliction of duty.

All we are asking of industry is for safer products. Once one becomes chemically injured, one must use them. Safer products exist. Their market is growing. Also, by switching to safer products, we've found another way to save on petroleum . . . and, based on the science of the South Coast Air Quality Management District (California) we'll also save on SMOG creation. (See "Chemicals in Home a Big Smog Source" by GARY POLAKOVIC / Los Angeles Times, Mar. 9, 2003, in which he writes: "Cleansers, cosmetics and other products pump 100 tons of pollutants daily into the Southland's air, ranking second to tailpipe emissions, studies show. "Ordinary household products such as cleansers, cosmetics and paints are now the Los Angeles region's second-leading source of air pollution, after auto tailpipe emissions, air quality officials say. . .")

We all are warned -- at least in California -- about breathing the chemicals at the gas pump, and we are warned about the harmful effects of liquor and tobacco, especially for pregnant women. At the very least, the public should be formally and adequately warned about the toxins hidden behind that benign-sounding word, FRAGRANCE.

We ALL are stakeholders when it comes to breathing.

Sincerely,

Barb Wilkie
President EHN

cc: FDA, NIOSH, NET

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EWG petitions FDA, June 2004
Support Cosmetic labeling petition,
Docket Number 2004P-0266
<http://www.ewg.org/reports/skindeep/>

EHN's fragrance petition, 99P-1340, remains open
<http://www.ehnca.org/FDApetition/bkgrinfo.htm>